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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,494	08/16/2001	Reid W. Von Borstel	1331-352	1560
23117	7590	11/03/2004		
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714				
EXAMINER LEWIS, PATRICK T				
ART UNIT		PAPER NUMBER		
1623				

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/930,494	Applicant(s) VON BORSTEL ET AL.	
	Examiner Patrick T. Lewis	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 21-22, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 16,17,42-46 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15,18-41 and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04212004, 06282004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on July 21, 2003 is acknowledged.
2. Claims 16-17, 42-46, and 50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 21, 2003. The restriction was made FINAL in the Office Action dated October 21, 2003.
3. This application contains claims 16-17, 42-46, and 50 are drawn to an invention nonelected without traverse in the Paper dated July 21, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's Responses Dated April 21, 2004 and April 22, 2004

4. In the response dated April 21, 2004, claims 1, 22, and 38 were amended. In the response dated April 22, 2004, claim 22 was amended. Claims 1-50 are pending. An action on the merits of claims 1-15, 18-41, and 47-49 is contained herein below.
5. The provisional rejection of claims 22, 24, 26, and 28-30 under 35 U.S.C. 101 as claiming the same invention as that of claims 48-53 and 62 of copending Application No. 09/763,955 has been withdrawn in view of applicant's arguments filed April 21, 2004.

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6. The provisional rejection of claims 1-15, 21, 23, 27, 31-32, 37-41, and 47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48-59 of copending Application No. 09/763,955 is maintained for the reasons of record as set forth in the Office Action dated October 21, 2003.

7. The objection to claims 22 and 38 was been rendered moot in view of applicant's amendment dated April 21, 2004.

8. The rejection of claims 1-15, 18-32, and 47-49 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in the Office Action dated October 21, 2003.

9. The rejection of claims 33-36 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in the Office Action dated October 21, 2003.

10. The rejection of claims 1-15, 18, 21-41, and 47-49 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of applicant's arguments dated April 21, 2004.

11. The rejection of claims 1-15, 18-32, and 37-41 under 35 U.S.C. 103(a) is maintained for the reasons of record as set forth in the Office Action dated October 21, 2003.

Rejections of Record Set Forth in the Office Action Dated October 21, 2003

12. Claims 1-15, 21, 23, 27, 31-32, 37-41, and 47 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48-59 of copending Application No. 09/763,955. Although the claims are not identical, they are not patentably distinct from each other.

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Applicant has not set forth arguments traversing the instant rejection.

13. Claims 1-15, 18-32, and 47-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of congenital mitochondrial disease, Alzheimer's Disease, Huntington's Disease, neuromuscular degenerative disease, and pathophysiological consequences of mitochondrial respiratory chain dysfunction, does not reasonably provide enablement for the prevention of congenital mitochondrial disease, Alzheimer's Disease, Huntington's Disease, neuromuscular degenerative disease, and pathophysiological consequences of mitochondrial respiratory chain dysfunction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments filed April 21, 2004, have been fully considered but they are not persuasive. Applicant argues that the idea of prevention does not relate to preventing or reversing genetic defects but, rather, compensating for them to prevent full clinical manifestation of their disorder.

During patent examination, the pending claims must be given their broadest reasonable interpretation consistent with the specification. This means that the words

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of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In the instant case, the specification does not provide a definition of "prevention". In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art. Furthermore the claims are rejected under 35 U.S.C. 112, first paragraph, because the disclosure is not enabled for the prevention of congenital mitochondrial disease, Alzheimer's Disease, Huntington's Disease, neuromuscular degenerative disease, and pathophysiological consequences of mitochondrial respiratory chain dysfunction not because the term "prevention" is indefinite. The specification does not provide sufficient support for applicant's claim that Alzheimer's Disease is prevented by the instant method. The specification does not provide sufficient support for applicant's claim that Huntington's Disease is prevented by the instant method. The specification does not provide sufficient support for applicant's claim that neuromuscular degenerative diseases are prevented by the instant method. The specification does not provide sufficient support for applicant's claim that pathophysiological consequences of mitochondrial respiratory chain dysfunction are prevented by the instant method.

14. Claims 1-15, 18-32, and 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Page et al. Proc. Natl. Acad. Sci. USA, 1997, Vol. 94, pages 11601-11606 (Page) in combination with von Borstel et al. US 6,316,426 B1 (von Borstel).

Applicant's arguments filed April 21, 2004 have been fully considered but they are not persuasive. Applicant argues that there is no indication or suggestion of

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evidence for mitochondrial respiratory chain dysfunction as a molecular basis for 5'-nucleotidase excess and one of ordinary skill in the art would not suspect that uridine or ribose would be useful in treating or preventing conditions caused by mitochondrial respiratory chain dysfunction.

Page teaches the treatment of patients described with a syndrome that included developmental delay, seizures, ataxia, recurrent infections, severe language deficit, and an unusual behavioral phenotype characterized by hyperactivity, short attention span, and poor social interaction with uridine. Developmental delay, seizures, ataxia, recurrent infections, severe language deficit, and an unusual behavioral phenotype characterized by hyperactivity, short attention span, and poor social interaction are "pathophysiological consequences of mitochondrial respiratory chain dysfunction". The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In the instant case, the prior art teaches the treatment of a population that is seen to overlap with the population treated by the instant invention with uridine rendering the instantly claimed method *prima facie* obvious.

Conclusion

15. Claims 1-50 are pending. Claims 16-17, 42-46, and 50 are drawn to a nonelected invention. Claims 1-15, 18-41, and 47-49 are rejected. No claims are allowed.

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16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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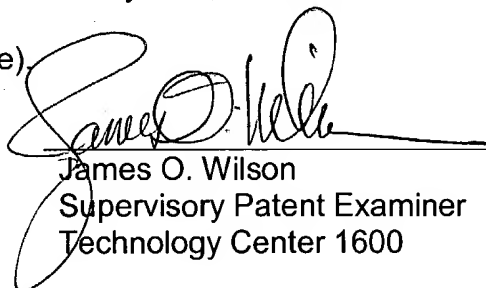
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday between 10 am - 2 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick Lewis, PhD
Examiner
Art Unit 1623



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